K083826

510(k) Summary

[in accordance with SMDA of 1990, 21 CFR 807 92(c)]

JAN 22 2009

Contact	Mr Hartmut Loch Regulatory Consultant Allez Spine, LLC 2301 Dupont Drive, Suite 510 Irvine CA 92612
Trade name	Allez Spine *Laguna*® Polyaxial Pedicle Screw System
Common name	Spinal Fixation System
Classification name	Appliance, Fixation, Spinal Interlaminal - § 888 3050 (KWP) Appliance, Fixation, Spinal Intervertebral - § 888 3060 (KWQ) Orthosis, Spinal Pedicle Fixation - § 888 3070 (MNI) Orthosis, Spondylolisthesis Spinal Fixation - § 888 3070 (MNH) All Class II, Orthopedic Device Panel 87
Product Code	KWP, KWQ, MNI & MNH
Device Description and Characteristics	The *Laguna*® Polyaxial Pedicle Screw System is intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral space The LAGUNA® Polyaxial Pedicle Screw System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor made for the individual case Multi axial screws are supplied in winged and non-winged configurations, in a variety of different length, and in 5mm, 6mm, and 7mm diameter sizes All sizes are able to receive 5 5mm connecting rods only The LAGUNA® Polyaxial Pedicle Screw System implant components are fabricated from medical grade titanium alloy per ASTM F136
Equivalence	The modified *Laguna*® Polyaxial Pedicle Screw System is substantially equivalent to the original *Laguna*® Pedicle Screw System, which is manufactured and marketed by Allez Spine, LLC
Indications	The LAGUNA® Polyaxial Pedicle Screw System is intended for posterior, non-cervical fixation for the following conditions degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i e fracture or dislocation), spinal stenosis, curvatures (i e scoliosis, kyphosis and/or lordosis), tumor pseudarthrosis, and/or failed previous fusion
Performance data	Biomechanical tests have been performed The test results were equivalent to other similar implants and are sufficient for *in vivo* loading

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Allez Spine, LLC
% Mr Hartmut Loch
2301 Dupont Drive, Suite 510
Irvine, CA 92612

JAN 22 2009

Re K083826
Trade/Device Name Laguna Polyaxial Pedicle Screw System
Regulation Number 21 CFR 888 3070
Regulation Name Pedicle Screw Spinal System
Regulatory Class II
Product Code MNH, MNI, KWP, KWQ
Dated December 16, 2008
Received December 23, 2008

Dear Mr Loch

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083826

Device Name(s) LAGUNA® Polyaxial Pedicle Screw System

Indications for Use

The LAGUNA® Polyaxial Pedicle Screw System is intended for posterior, non-cervical fixation for the following conditions degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis; trauma (i e fracture or dislocation), spinal stenosis, curvatures (i e scoliosis, kyphosis and/or lordosis), tumor pseudarthrosis, and/or failed previous fusion

Prescription Use ✓ AND/OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083826

Page 1 of 1